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09/534,946	03/24/2000	Frank R. Ruderman	MBHB00-203	1964
20306 7590 01/30/2009 MCDONNELL BOEHNNEN HULBERT & BERGHOFF LLP 300 S. WACKER DRIVE 32ND FLOOR CHICAGO, IL 60606				
EXAMINER NAJARIAN, LENA				
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1 UNITED STATES PATENT AND TRADEMARK OFFICE  
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4 BEFORE THE BOARD OF PATENT APPEALS  
5 AND INTERFERENCES  
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8 *Ex parte* FRANK R. RUDERMAN and DAVID T. SHEWMAKE  
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10 Appeal 2008-1943  
11 Application 09/534,946  
12 Technology Center 3600  
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16 Decided: January 30, 2009  
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19 *Before* MURRIEL E. CRAWFORD, DAVID B. WALKER, and JOSEPH A.  
20 FISCHETTI, *Administrative Patent Judges*.

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22 CRAWFORD, *Administrative Patent Judge*.  
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25 DECISION ON APPEAL  
26

27 STATEMENT OF THE CASE

28 Appellants appeal under 35 U.S.C. § 134 (2002) from a Final  
29 Rejection of claims 22 to 28 and 38. We have jurisdiction under 35 U.S.C.  
30 § 6(b) (2002).

1 Appellants invented a cardiovascular healthcare management system  
2 that identifies patients who do not have hyperlipidemia based on total LDL  
3 cholesterol and total HDL cholesterol, but are in need of treatment. The  
4 cardiovascular healthcare management system includes a diagnostic engine  
5 which analyzes patient test results for subclasses of LDL and HDL including  
6 HDL 2b (Specification 1, 14 to 15).

7 Claim 38 under appeal reads as follows:

8 38. A cardiovascular healthcare  
9 management system comprising:

10 (a) an infomediary site having databases for  
11 cardiovascular healthcare management which  
12 includes a database of test results of concentration  
13 of subclasses of LDL particles and subclasses of  
14 HDL particles from at least 900 cardiovascular  
15 patients;

16 (b) a data entry interface for receiving  
17 patient personal data and test results for  
18 concentration of subclasses of LDL particles and  
19 subclasses of HDL particles storing the data and  
20 results in the infomediary site databases;

21 (c) a diagnostic engine for analyzing patient  
22 test results for subclasses of LDL particles,  
23 subclasses of HDL particles data and identifying  
24 patients who do not have hyperlipidemia based on  
25 total LDL cholesterol and total HDL cholesterol,  
26 but are in need of treatment; and

27 (d) wherein the subclasses of LDL particles  
28 and subclasses of HDL particles are levels  
29 determined by segmented gradient gel  
30 eletrophoresis and wherein the particle sub-classes  
31 include HDL 2b.  
32



FINDINGS OF FACT

FF1. Appellants disclose at page 1 of the Specification that:

The art describes cardiovascular risk factors such as age, smoking, weight, family history, blood pressure, lipid profiles including low density lipoprotein (LDL) and high density lipoprotein (HDL) and subclasses (fractions) of LDL and HDL. Methods for measuring these factors and relating them to patient treatment are also known.

FF2. Levin discloses a system for managing coronary disease having databases for cardiovascular healthcare management which includes database test results including LDL and HDL concentrations to calculate total cholesterol (Figure 4, col. 8, ll. 21 to 47).

FF3. Otvos discloses that commercially prepared lipid panels only include total cholesterol, total HDL and total LDL rather than LDL and HDL subclass information. (Col. 1, ll. 43 to 48). Otvos discloses that NMR analysis provides information about four subclasses of LDL and five subclasses of HDL (col. 1, ll. 48 to 52). Otvos discloses that various subclasses of lipoproteins may provide more reliable markers of the metabolic conditions that predispose individuals to a greater or lesser risk of heart disease (col. 1, ll. 59 to 62). Otvos discloses that using LDL subclass information may reveal a patient that does not have lipid profile indicating high risk when the total LDL is considered, but is still in need of treatment (col. 16, ll. 53 to 57). In Figure 11, Otvos depicts that an examination of the total HDL concentration of 32 mg/dl results in a positive risk factor when the large HDL subclass which is 11 nmol/L is examined, it too results in a

1 positive risk factor. As such, Otvos does not disclose that an advantage can  
2 be achieved by examining the large HDL subclass.

3 Krauss does not disclose a diagnostic engine for analyzing patient test  
4 results for subclasses of LDL particles, subclasses of HDL particles, and  
5 identifying patients who do not have hyperlipidemia based on total LDL  
6 cholesterol and total HDL cholesterol, but are in need of treatment wherein  
7 the particle subclasses include HDL 2b.

8  
9 PRINCIPLES OF LAW

10 The test for obviousness is what the combined teachings of the  
11 references would have suggested to one of ordinary skill in the art. *See In re*  
12 *Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006); *In re Young*, 927 F.2d 588,  
13 591 (Fed. Cir. 1991) and *In re Keller*, 642 F.2d 413, 425 (CCPA 1981).

14 Rejections on obviousness grounds cannot be sustained by mere  
15 conclusory statements; instead, there must be some articulated reasoning  
16 with some rational underpinning to support the legal conclusion of  
17 obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). A finding of  
18 obviousness can be based on the effects of demands known to the design  
19 community or present in the marketplace; or the background knowledge  
20 possessed by a person having ordinary skill in the art, as support for his  
21 conclusion that there existed at the time of the invention an apparent reason  
22 to modify the sleeve nut and grommet of Borst in the manner claimed. *See*  
23 *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, \_\_\_, 127 S. Ct. 1727, 1740-41  
24 (2007).

ANALYSIS

*Rejection of claims 22, 24 to 28 and 38*

We will not sustain the Examiner's Rejection. Although we agree with the Examiner that Otvos discloses that more risk factors can be determined when subclasses of LDL are examined, Otvos does not disclose that examination of HDL subclasses leads to the same advantage. In fact, a review of Figure 11 of Otvos indicates that the total HDL concentration lead to one risk factor and the large HDL also lead to one risk factor and as such does not disclose that an advantage is obtained by examining HDL subclasses. And while the Appellants' Specification discloses that subclasses of LDL or HDL may be considered risk factors, the Specification does not disclose which subclass concentrations are considered risk factors. Further, none of the references discloses that the subclasses analyzed must include HDL 2b or any reason to include HDL 2b. Therefore, there is no reason to include subclass HDL 2b in Levin as modified by Otvos system.

In view of the foregoing, we will not sustain the Examiner's rejection of claim 38 and claims 22 and 24 to 28 dependent thereon.

We will also not sustain the Examiner's rejection of claim 23 as being unpatentable over Levin, Otvos, AAPA, Krauss and Surwit because claim 23 depends from claim 38, and Surwit does not cure the deficiencies noted above for the Levin, Otvos, Krauss, AAPA combination.

CONCLUSION OF LAW

On the record before us, Appellants have shown that the Examiner erred in rejecting the appealed claims.

DECISION

The Examiner's rejection of claims is reversed.

REVERSED

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